UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

BRIAN COURTER, et al., Plaintiff, v. CYTODYN, INC., et al., Defendants.	CASE NO. C21-5190 BHS ORDER

THIS MATTER is before the Court on defendants CytoDyn, Inc., Michael Mulholland and Scott Kelly's motion to dismiss plaintiff Brian Courter,[1] et al.'s second amended class action complaint, Dkt. 116. Defendant Pourhassan joins the motion, Dkt. 123.

The putative plaintiff class asserts four Securities Act claims based on the defendants' allegedly false and misleading statements about CytoDyn's Investigational

[1] There are six named plaintiffs, all seeking to represent a class of similarly situated purchasers of CytoDyn stock during the Class Period, between March 27, 2020, and March 30, 2022. This Order refers to the plaintiffs as "Courter" in the singular for clarity and ease of reference, unless the context requires otherwise.

New Drug (IND), "Leronlimab." Defendants move to dismiss the bulk of Courter's claims.

I. BACKGROUND

CytoDyn[2] is a Vancouver, Washington based biotechnology company. Its primary drug candidate is Leronlimab, which it describes as a "humanized monoclonal antibody" that it is developing for a variety of potential uses. Dkt. 116 at 7. Mulholland was CytoDyn's Chief Financial Officer (CFO) from December 2012 to May 2021. Kelly was a CytoDyn director, Chairman of the Board, and Chief Science Officer over time, from April 2017 to December 19, 2022. Nader Pourhassan was the CEO, president, and a member of the board from 2101 to January 2022.

Courter alleges that CytoDyn, Pourhassan, Mulholland, and Kelly materially misled investors about the progress and success of its ongoing efforts to obtain FDA approval for use of its sole drug, "Leronlimab," as a treatment for HIV and, later, for COVID-19. Courter alleges CytoDyn made false statements and failed to disclose important information to increase CytoDyn's stock price, and that he was damaged when the price fell because the true, dismal state of those efforts was revealed.

Courter alleges CytoDyn's false statements arose in two overlapping contexts, over two years. The first context is CytoDyn's efforts to persuade the market that its HIV "biologic license application (BLA)" to the FDA was complete and that approval was imminent, to prop up CytoDyn's stock price. Courter contends that CytoDyn misled

[2] The Order similarly refers to all four named defendants as "CytoDyn" except where the context requires otherwise.

investors about its lengthy efforts to obtain FDA approval for Leronlimab as an HIV treatment. He contends CytoDyn publicly stated on April 27, 2020, that the HIV BLA was "complete" when it was not; CytoDyn had not provided data, information and analyses the FDA had already told CytoDyn was required. Courter alleges the FDA privately told CytoDyn on April 29, 2020, that its BLA submission was *not* complete and asked it to "take responsibility for the misinformation." Dkt. 132 at 14 (citing Courter's second amended complaint, Dkt. 103, at 41).

Courter alleges that the stock price spiked because of CytoDyn's announcement, and that Pourhassan and Kelly exercised options to sell stock for almost $19 million between April 30 and May 4, 2020. CytoDyn did not acknowledge that its HIV BLA was in fact incomplete until May 4, which Courter contends predictably sent the stock price back down. CytoDyn supplemented its HIV BLA submission in May and told investors that the BLA was now complete, even though it knew it lacked the required safety and dosage data.

On July 8, 2020, the FDA sent CytoDyn a nonpublic "Refuse to File (RTF)" letter, explaining that the May submission "had numerous omissions and inadequacies so severe as to render the application incomplete[.]" Dkt. 132 at 14 (citing Dkt. 103 at 45–46). Courter alleges that the letter meant that CytoDyn could not submit a complete HIV BLA without conducting an additional clinical trial. CytoDyn publicly announced it had received the RTF letter, but Courter alleges it knowingly misrepresented the letter's contents and its ability to timely resubmit the BLA. *Id*. On July 13, 2020, CytoDyn issued a Press Release (and held an investment community conference call) asserting that

the FDA would not require more clinical trials, and that CytoDyn was "confident it can provide all information requested by the FDA." *See* Dkt. 177 at 24–28 and 30–48. Courter asserts that these statements were knowingly false.

The second context for CytoDyn's allegedly false statements relates to its efforts to obtain FDA approval to use Leronlimab as an Investigational New Drug (IND) to treat COVID-19. Courter's claims arise primarily from statements related to its early emergency IND (eIND) use, and two subsequent clinical trials, CD10 and CD12. CytoDyn released the results of CD10 at the end of July 2020. While the study missed its primary endpoint, Courter asserts that CytoDyn falsely assured investors that the "more important" and "statistically significant" results for the National Early Warning Score2 (NEWS2) scale secondary endpoint demonstrated that Leronlimab was effective and that CytoDyn had "requested Emergency Use Authorization (EUA)" based on the results of CD10. Dkt. 132 at 15. Courter contends that these statements were false; CytoDyn knew the NEWS2 data was instead clinically meaningless, that CD10 did not support further FDA action, and that CytoDyn had not requested EUA. CytoDyn admitted this latter point on September 16, 2020, and the stock declined. *Id*.

Courter contends that CytoDyn's efforts continued with a second clinical trial, CD12, which tested Leronlimab's efficacy for critically ill COVID-19 patients. He alleges CytoDyn "unblinded" this clinical trial on February 12, 2021, and that CD12 missed all its endpoints. Nevertheless, CytoDyn sent the FDA an Executive Summary seeking EUA for critically ill COVID-19 patients based on analysis of CD12 subgroups four days later. On February 18, the FDA denied the EUA because the subgroup analyses

did not support efficacy and CytoDyn's emphasis on favorable trends in them was "potentially misleading." *Id*. CytoDyn revised and resubmitted its request for EUA on February 23. On February 25, the FDA responded that CD12 was not sufficient to support EUA and that the trial did not demonstrate Leronlimab's efficacy. *Id*.

Courter alleges that CytoDyn told investors about the CD12 results on March 8, 2021, and the stock price declined. But CytoDyn also told investors that CD12 demonstrated Leronlimab was effective and that it had sought EUA. Courter alleges that the FDA issued in response a "devastating" "Statement on Leronlimab" on May 17, 2021, explaining that the currently available data did not support the clinical benefits of Leronlimab for COVID-19. Dkt. 117 at 5. He asserts that CytoDyn nevertheless continued to falsely represent to investors that the drug was on a path to FDA approval, and Pourhassan falsely told investors that none of CytoDyn's prior statements were inconsistent with the FDA's Statement. Dkt. 132 at 16.

Courter contends that CytoDyn continued to publicly, and falsely, claim that the FDA was not requiring another clinical trial for the HIV BLA, and that CytoDyn already had the data needed to complete the BLA. *Id*. Instead, he claims, CytoDyn and its officers had internally recognized that they did not have the necessary data, and that they would need another trial—a process complicated further by the fact that it had lost access to some of its prior data held by a third party, Amarex. *Id*. He alleges that CytoDyn knew it faced a risk of a "clinical hold" for both its HIV and COVID-19 Leronlimab programs due to the missing and inaccessible data by September 2021, but did not admit that fact to investors until March 30, 2022 (the last day of the class Period), when it announced that

the FDA had placed "clinical holds" on both the HIV and COVID-19 IND programs, prompting another decline in the stock price. *Id*.

Courter asserts that CytoDyn's efforts to increase the price of CytoDyn's stock through false representations about the success of Leronlimab violated the Securities Exchange Act, and he asserts four claims: a Section 10b (SEC Rule 10b-5(b)) claim against all defendants for "making" false and misleading statements about CytoDyn's efforts to obtain FDA approval for Leronlimab (Count I); a Section 10b (SEC Rule 10b-5(a) and (c) claim against all defendants for a fraudulent scheme to "promote" the misleading and false statements (Count II); a Section 20a claim against the three individual defendants as "control persons" liable for CytoDyn's 10b violations (Count III); and a section 20A claim against the individual defendants for insider trading (Count IV). Courter seeks to represent a class of similarly damaged investors between March 27, 2020, and March 30, 2022. Dkt. 103.

CytoDyn seeks dismissal of most of Courter's claims, arguing primarily that he has not sufficiently alleged that the statements upon which he relies were false or misleading, measured against the "formidable" pleading requirements of the Private Securities Litigation Reform Act (PSLRA) and Federal Rule of Civil Procedure 9(b). Id. at 9 (citing *Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1064 n.7 (9th Cir. 2008)). It argues that Courter had failed to plead specific facts supporting a strong inference of scienter and emphasizes that, in contrast to the Court's "typical" Rule 12(b)(6) analysis, it must consider plausible, nonculpable explanations for the defendants' conduct, and account for "plausible opposing inferences." Dkt. 116 at 10

(citing *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 323–24 (2007). Its defense rests primarily on its claim that Courter must plead scienter for *each defendant*, and must set forth, "in great detail, facts that constitute strong circumstantial evidence of deliberately reckless or conscious misconduct." *Id*. (citing *Glazer Capital Mgmt., LP v. Magistri*, 549 F.3d 736, 745 (9th Cir. 2008). CytoDyn argues that Courter's complaint ignores the context in which the many statements at issue were made. It asks the Court to Dismiss the bulk of Courter's claims against it, Mulholland, and Kelly. Dkt. 116. Pourhassen joins most of the motion and seeks dismissal of most of Courter's claims against him. Dkt. 123.

The issues are addressed in turn.

II. DISCUSSION

A. Pleading standards for Courter's Section 10b claims.

Dismissal under Fed. R. Civ. P. 12(b)(6) may be based on either the lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory. *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1990). A plaintiff's complaint must allege facts to state a claim for relief that is plausible on its face. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A claim has "facial plausibility" when the party seeking relief "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. Although the court must accept as true the complaint's well-pled facts, conclusory allegations of law and unwarranted inferences will not defeat an otherwise proper 12(b)(6) motion to dismiss. *Vasquez v. Los Angeles Cnty.*, 487 F.3d 1246, 1249 (9th Cir. 2007); *Sprewell v.*

Golden State Warriors, 266 F.3d 979, 988 (9th Cir. 2001). "A plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (cleaned up). This requires a plaintiff to plead "more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555).

On a 12(b)(6) motion, "a district court should grant leave to amend even if no request to amend the pleading was made, unless it determines that the pleading could not possibly be cured by the allegation of other facts." *Cook, Perkiss & Liehe v. N. Cal. Collection Serv.*, 911 F.2d 242, 247 (9th Cir. 1990). However, where the facts are not in dispute, and the sole issue is whether there is liability as a matter of substantive law, the court may deny leave to amend. *Albrecht v. Lund*, 845 F.2d 193, 195–96 (9th Cir. 1988).

CytoDyn correctly contends the PSLRA and Federal Rule of Civil Procedure 9 require Courter to allege with specificity six elements to plausibly plead a Section 10(b) claim: (1) a material misstatement or omission; (2) scienter; (3) purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation. Dkt. 116 at 9 (citing *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008)). It argues that Courter must identify each misleading statement and the reason why it is misleading, including an articulation of facts showing that the statement was false when it was made. *Id.*

B. Count I – Section 10(b) false statements (Rule 10b-5(b)).

Courter's primary claim is that CytoDyn's statements about its ongoing efforts to obtain FDA approval for the use of Leronlimab to treat HIV and then COVID-19 were false and misleading, and violated Section 10(b) of the Securities Act. His operative second amended complaint thoroughly catalogues the public statements CytoDyn made through Pourhassan and others. Dkt. 103. He argues he has amply pled the elements of his Section 10(b)-based claims: defendants "made," (Rule 10b-5(b), "disseminated" or "promoted," (Rule 10b-5(a) and (c)), materially false and misleading statements regarding CytoDyn's HIV BLA and COVID-19 IND with scienter, and the stock price declined when the truth was revealed over "six partially corrective events," which removed the stock price inflation caused by the falsities. Dkt. 132 at 17.

The motion is unusual in that CytoDyn's statements (and the FDA's responsive statements and actions) are well-documented, and CytoDyn does not dispute that they were made. Instead, it argues that, viewed in context, most of the statements are not actionable.

The Court agrees that the context is important but concludes that in context Courter has plausibly pled that CytoDyn's statements were false or misleading. The motion to dismiss Courter's Rule 10b-5(b) is **DENIED**.

1. CytoDyn's HIV BLA statements.

CytoDyn argues that Courter has not sufficiently alleged that its statements regarding its BLA were materially false or misleading. It argues that it did in fact submit its HIV BLA to the FDA on April 27, 2020, and supplemented its data in support of that

filing May 11, and that nothing in its statements about those events "guaranteed" that the FDA would approve the BLA. Dkt. 116 at 10. Instead, it contends, the challenged statements suggested to a reasonable investor that there would be additional dialogue with the FDA: "*As a next step*, the FDA will start reviewing the BLA for completeness[.] … *After the BLA submission is deemed completed*, the FDA assigns a [PDUFA] goal date." *Id*. (emphasis in CytoDyn's motion). It argues reasonable investors would anticipate that such a submission would lead to a dialogue involving the presentation of differing views. *Id*. (citing *In re Dynavax Sec. Litig*., 2018 WL 2554472, at *7 (N.D. Cal. June 4, 2018) and *Tongue v. Sanofi*, 816 F.3d 199, 211 (2d Cir. 2016)).

Courter responds that CytoDyn's unequivocal statement that the BLA was "complete" was materially false and misleading; CytoDyn lacked data, information, and analyses that the FDA had already told it would be critical components of a complete BLA submission, and CytoDyn in fact never provided that information. Dkt. 132 at 18. Courter alleges that when CytoDyn made its public statements, it possessed the FDA's non-public correspondence advising it that it needed specific safety and dosage data, and that it did not have that data, and that its April BLA submission cover letter specifically identified the missing information. *Id*. And it emphasizes that by April 30 the FDA had told Pourhassan it was concerned his statements about the BLA's status as "complete" were "misleading." It argues that the statements were therefore false or misleading when they were made. *Id*. (citing *Glazer Capital Mgmt., L.P. v. Forescout Techs., Inc.*, 62 F.4th 747, 764 (9th Cir. 2023) ("A statement is false or misleading if it directly contradict[s] what the defendant knew at the time or omits material information"); and *Zak v. Chelsea*

Therapeutics Int'l, Ltd., 780 F.3d 597, 610 (4th Cir. 2015) (allegations permitted strong inference that defendants "misled investors by failing to disclose critical information received from the FDA…while releasing less damaging information [] they knew was incomplete."). Courter argues, persuasively, that CytoDyn's claim that investors knew that the dialogue was "ongoing" does not negate the Courter's allegation that the FDA had already told it that its submission was far from complete.

The heightened pleading standard does not require Courter to allege that CytoDyn "guaranteed" that the FDA would approve Leronlimab; it requires him to plausibly allege that CytoDyn's statements were knowingly false or misleading when made. Courter correctly contends that investors' presumed knowledge of an ongoing dialogue with the FDA does not negate the fact that CytoDyn's statements about what had already occurred were incomplete and untrue; it had not provided the FDA basic, critical data it knew was needed to make its BLA complete.

The same is true with respect to CytoDyn's statements after it received the FDA's RTF letter. Courter has specifically and plausibly pled that the BLA was still not "complete" after the May 2020 submission, that the FDA did not seek only "additional information" about an ongoing trial, and that it had all the data it required and thus would not have to do any more clinical trials. Courter asserts that these statements were materially misleading and false: the submission was not complete, the FDA's RTF letter sought information it had been seeking since 2018, and it did *not* inform CytoDyn that additional clinical trial were unnecessary. Instead, Courter has specifically and plausibly pled that CytoDyn knew, and did not disclose, that it did not have the safety and dosage

data the FDA insisted it needed, and that it could not get that data without additional trials. Dkt. 132 at 19–20 (citing *Schueneman v. Arena Pharm., Inc.*, 840 F.3d 698, 704 (9th Cir. 2016) (because Arena did not have "all of the data in hand," it "could not, in fact, support" its statements when made.)). *See also In re CV Therapeutics, Inc. Sec. Litig*., 2004 WL 1753251, *7 (N.D. Cal. Aug. 5, 2004) (statements misrepresenting data in NDA and "affirm[ations] that nothing…made [defendant] believe that another study would be needed" actionable); *Frater v. Hemispherx Biopharma, Inc.*, 996 F. Supp. 2d 335, 346 (E.D. Pa. 2014) (false statements about FDA's position on new trial actionable); *Shanawaz*, 348 F. Supp. 3d at 325 (claims sustained where data at issue was not "submitted…to the FDA [] despite" defendants' statements). *Id*.

Courter also argues that because CytoDyn disclosed some of the RTF letter's "outstanding review issues," it was "obligated to share the other significant review issues." *Id*. at 20 (citing *Pardi v. Tricida, Inc.*, 2022 WL 3018144, *13 (N.D. Cal. July 29, 2022). He argues that CytoDyn "hid the ball" from investors by the FDA's prior guidance about its BLA was an explicit reason for the RTF letter. *Id.* (citing *Pardi* at *13, and *In re Atossa Genetics Inc. Sec. Litig.*, 868 F3d 784, 797-98 (9th Cir. 2017) (statements about FDA letter "misleading" where Defendants "studiously avoided disclosing" material information it contained).

CytoDyn argues primarily that it disclosed the RTF letter, which as Courter emphasizes, was itself the most important and disappointing news about the BLA, and as Courter alleges, CytoDyn's stock price fell on that news. It contends that Courter inappropriately focuses on sentences and phrases "divorced" from the context of the

unambiguously negative RTF letter. Dkt. 116 at 12 (citing *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 985 (9th Cir. 2008) (statement is misleading only "if it would give a reasonable investor the 'impression of a state of affairs that differs in a material way from the one that actually exists'")).

Courter correctly contends that this argument is a "truth on the market (TOTM)" affirmative defense, a method of refuting an alleged misrepresentation's materiality. Dkt. 132 at 21 (citing *Amgen Inc. v. Conn. Ret. Plans & Tr. Funds*, 568 U.S. 455, 481 (2013)). He argues that the TOTM defense excuses a defendant's failure to disclose material information ***only*** where a defendant shows ***that*** information was publicly transmitted … with a degree of intensity and credibility sufficient to effectively counterbalance any misleading impression created by [defendants'] one-sided representations." *Id*. at 21 (citing *In re Amgen Inc. Sec. Litig.*, 544 F. Supp. 2d 1009, 1025 (C.D. Cal. 2008) (emphasis added)). Indeed, it asserts that TOTM "is intensely fact-specific, so courts rarely dismiss…on this basis," *id.*, and "defendants bear a heavy burden of proof." *Id.* (citing *Provenz v. Miller*, 102 F.3d 1478, 1493 (9th Cir. 1996)).

CytoDyn argues that its statements that the BLA was "complete" were not misleading because there is no reason an investor would view them as material; they were about the prior BLA submission, upon which the FDA had already taken negative action. Dkt. 137 at 8. It argues it was not misleading to say the FDA would require no new clinical trials because, as Courter acknowledges, the FDA did not say that further trials were required. Instead, additional data was required, and CytoDyn simply stated that "planned" to resubmit with additional data. *Id*.

But Courter has plausibly pled that CytoDyn knew it did not have such data, and could not get, and thus submit, such data without conducting additional clinical trials. CytoDyn's filings do not claim that it could have done so, and it is apparently undisputed that it did not do so. He has plausibly alleged that CytoDyn's statements about its BLA after the RTF letter gave reasonable investors an impression of a state of affairs that differed in a material way from the one that existed. *See Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 985 (9th Cir. 2008). CytoDyn's argument that Courter's claims rely on a "fraud in hindsight" theory, because CytoDyn's "predictions" about the future turned out to be wrong, Dkt. 137 at 8, is similarly unpersuasive. His claim is not that CytoDyn's statements about its BLA turned out to be wrong when the FDA placed a clinical hold on its HIV program two years later. Instead, he plausibly claims that CytoDyn's statements in the aftermath of the RTF letter were false and misleading when they were made; the BLA submission was never complete, a compete submission always required data that CytoDyn did not have and could not get without an additional clinical trial.

Even against the heightened pleading standards applicable to his claim, Courter has plausibly alleged that CytoDyn's statements regarding the HIV BLA were false and misleading, based on what CytoDyn knew at the time the statements were made. CytoDyn's motion to dismiss Count I based on its BLA statements is **DENIED**.

2. CytoDyn's COVID-19 statements.

Courter asserts that CytoDyn misled investors about Leronlimab's potential to treat COVID-19 in the respects: (1) the FDA's emergency use authorization, (2) the results of the CD10 clinical trial, and (3) the results of the CD12 clinical trial.

CytoDyn also seeks dismissal of Courter's Section 10(b) claim based on its statements about its attempts to obtain FDA approval to use Leronlimab to treat COVID-19. It argues the complaint ignores the more important context of the challenged statements. Dkt. 116 at 12.

a. CytoDyn's COVID-19 eIND statements.

First, CytoDyn argues that it disclosed that the FDA would no longer issue eINDs and that it instead recommended it conduct a randomized controlled trial. It argues that Courter has failed to plausibly plead why this plainly negative news would not be dispositive to a reasonable investor. Dkt. 116 at 12. It argues Courter's claims that the accompanying statements were misleading fail because federal securities law does not require companies to disparage their own product lines, Dkt. 116 at 13 (citing *Kane v. Madge Networks N.V.*, 2000 WL 33208116, at *8 (N.D. Cal. May 26, 2000), *aff'd sub nom. Kane v. Zisapel*, 32 F. App'x 905 (9th Cir. 2002)), especially when it has provided accurate hard data from which investors can draw their own conclusions. *Id*. (citing *Romine v. Acxiom Corp.*, 296 F.3d 701, 708 (8th Cir. 2002)).

Courter argues that CytoDyn falsely and misleadingly told investors that the eIND data "demonstrated" Leronlimab's "mechanism-of-action" (MoA)—how it worked—and its efficacy, supported the FDA's decisions regarding the COVID-19 IND, and supported

EUA. He asserts CytoDyn knew at the time it made the statements it knew they were materially false because it knew from nonpublic FDA correspondence that these claims were false: CytoDyn's data was "in-vitro," "uninterpretable," and "uncontrolled," and thus could not "demonstrate" Leronlimab's efficacy or its MoA, and could not support further FDA action, including EUA. Dkt. 132 at 23.

Courter argues that statements are actionable where "[c]ontrary to [defendant's] representations to investors[,] it was not true that [in-vitro data] demonstrated" a drug's efficacy, Dkt. 132 at 23 (citing *Arena*, 840 F.3d at 708), and where defendants publicly tout trial results the knew were likely unreliable. *Id*. (citing *Khoja*, 899 F.3d at 1010). He argues, persuasively, that CytoDyn falsely told investors it "understood how the drug worked." *Id*. (citing *In re Regeneron Pharm., Inc. Sec. Litig.*, 2005 WL 225288, *9 (S.D.N.Y. Feb. 1, 2005)).

Courter argues CytoDyn's public statements were false or misleading because while it knew the eIND data was clinically meaningless, it continued to misrepresent the import of the data including implying that it supported the FDA's decisions: the FDA gave a "green light" to CD10 and CD12 based on the eIND data. *Id*. Courter argues the evidence the statements were material to investors is that analysts seized on them ("FDA may endorse Leronlimab based on eIND alone;" report increasing target price, touting Leronlimab's "newly discovered effectiveness in treating COVID-19"), and the stock price went up in response. Dkt. 132 at 24. He accurately argues that information about a potential drug's efficacy and the likelihood of FDA approval is critical and thus material,

and that CytoDyn's statements that the eINDs demonstrated efficacy were false because the FDA had expressed doubts about the reliability of its data. Dkt. 132 at 24

Courter responds to the claim CytoDyn was not obligated to focus on the disappointing part of the news by citing on-point cases explaining that once it chose to tout "positive" information, it was obligated to disclose the adverse information. *Id*. at 25 (citing *Arena*, 840 F.3d 706–706). Courter argues that, in context, CytoDyn was required to disclose that the eIND data was likely unreliable, and that the FDA had already told it that results with a high degree of uncertainty would not support FDA action. *Id*. (citing *Khoja*, 899 F.3d at 1010). He argues once it chose to speak on its interactions with the FDA, CytoDyn was obligated to disclose the FDA's concerns that it needed in-vivo clinical data to render its statements not misleading. *Id*. (citing *Freedman v. St. Jude Med., Inc.*, 4 F. Supp. 3d 1101, 1114 (D. Minn. 2014); *Arena*, 840 F.3d 705-06; *Amylin*, 2003 WL 21500525 at *8 (defendants obligated to disclose the need for "validat[ion] through a clinical study" and lack of "in-vivo [or] clinical data.")).

Courter also persuasively disputes CytoDyn's claim that the news that the FDA would not authorize further EUA for COVID-19 was "dispositive" to a reasonable investor, making immaterial any accompanying optimism. He asserts that this version of CytoDyn's TOTM defense fails because the statements were made prior to the date (June 2, 2020) that the FDA's eIND decision was made public. *Id*. (citing *City of Birmingham Relief and Ret. Sys. v. Acadia Pharm., Inc.*, 2022 WL 4491093, *11 (S.D. Cal. Sept. 27, 2022) (TOTM defense rejected where information was "release[d]… after the first allegedly misleading statement"). And for statements after that disclosure, the FDA's

decision not to authorize further eINDs was not the omitted material; it was the fact the data gathered from the eINDs already conducted was meaningless.

Finally, Courter argues that Pourhassan's June 2020 statements about the eINDs were actionable because they were created the misleading impression that the FDA's decision reflected a belief the Leronlimab was effective for COVID-19. In truth, Courter contends, the FDA shut down CytoDyn's "*de facto*" Leronlimab "compassionate use study" premised on an unacceptably high number of eINDs, to ensure CytoDyn "focused" on obtaining in-vivo clinical data that it did not yet have, to demonstrate efficacy. Dkt. 132 at 26. And, Courter emphasizes, he plausibly pleads that the FDA told CytoDyn that its statements were misleading and required it to "acknowledge that the [FDA] has repeatedly informed CytoDyn that [it has] not been able to establish clinical proof-of-concept for Leronlimab for COVID-19" and that "[u]ncontrolled [e]IND data are not adequate[.]" He argues that such a rebuke in response to its statements make the statements materially false. *Id*. (citing *In re Dura Pharms. Inc. Sec. Litig.*, 548 F. Supp. 2d 1126, 1137 (S.D. Cal. 2008)). He argues that revealing only the FDA's decision to stop authorizing eINDs "did not effectively counter-balance the misleading impression created by" CytoDyn's statements. *Id*. (citing *In re NeoPharm, Inc. Sec. Litig.*, 2003 WL 262369, *13 (N.D. Ill. Feb. 7, 2003) (TOTM defense rejected where "defendants fraudulently downplayed the significance of [the news]" by not disclosing serious "problems plaguing" drug)). The same is true here.

CytoDyn replies that its statements did reveal the relevant negative results and that he has not pled or explained why investors were misled by its focus on the data it viewed

as positive, given its contemporaneous disclosure of the disappointing nature of the results as a whole. Dkt. 137 at 9. Here, it argues that Courter's "desire for additional context" does not render its statements misleading. *Id*.

The Court does not agree. Courter has plausibly and specifically pled that CytoDyn misleadingly spun the FDA's adverse decision as a demonstration of Leronlimab's efficacy, and a "green light" to proceed with clinical trials. The FDA understandably rebuked it because these statements were contrary to the truth, which was that there was no evidence of efficacy and formal trial were required to obtain usable data. CytoDyn's motion to dismiss Courter's Rule 10b-5(b) claim based on statements CytoDyn made about the COVID-19 eINDs is **DENIED**.

b. CytoDyn's CD10 statements.

Courter alleges that CytoDyn's misleading statements about Leronlimab's use as a treatment for COVID-19 and the success of efforts to obtain FDA approval continued with respect to its CD10 Phase 2 clinical trial, between July 30, 2020, and April 14, 2021. Dkt. 132 at 26. He argues that Pourhassan misleadingly announced the CD10 had "positive efficacy results, a "statistically significant" difference "between Leronlimab and placebo," allowing it to seek EUA for COVID-19. Dkt. 132 at 26–27. Courter argues that CytoDyn created a misleading impression that CD10 was a success, and that it supported EUA, stating that it "demonstrated statistically significant results" in the "key NEWS2 secondary endpoint," and that it was the "first drug actually worked on COVID-19." *Id.* at 27. CytoDyn also announced it had "requested" EUA, based on CD10. Courter alleges that CytoDyn admitted to the FDA that the NEWS2 "mean baseline values were too low

to observe a clinically meaningful difference after treatment." He alleges that this means CytoDyn already knew that Leronlimab was in fact no more effective than a placebo. He contends that as a result, CytoDyn "fabricated" data to demonstrate efficacy, touting the NEWS2 data to investors when it knew the FDA would not accept it. He claims these statements are actionable *Id*. (citing *In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 1019 (S.D. Cal. 2005) ("Defendants committed fraud by publicly reporting [] results" that were "so statistically flawed to lack clinical significance" and "portraying the results" "in an unduly optimistic light.") *Id*. at 27.

CytoDyn argues again that it disclosed the relevant negative news: CD10 failed to meet it primary endpoint. Dkt. 116 at 13 (citing August 11, 2020, Press Release, Dkt. 117-3). It argues that, again in context, Courter has not plausibly alleged that its emphasis on the few pieces of data that it regarded as positive[3] were misleading, given the contemporaneous disclosure of the disappointing news regarding the study as whole. *Id*. at 13–14 (citing *Biogen Sec. Litig.*, 179 F.R.D. 25, 39 (D. Mass. 1997) (omissions not material where company disclosed "the most relevant and disappointing aspect of the [trial] results – the failure to reach the primary endpoint")).

Courter responds that though it disclosed the negative news, CytoDyn's accompanying statements were nevertheless false and misleading. He argues that statements touting positive trial data are actionable if the defendant knows but does not

[3] One such statement is: "We discovered that the secondary endpoint, that we believe is even more important than our primary endpoint, and we have achieved a statistically significance value which is the so-called NEWS2." Dkt. 116 at 13.

disclose that the available evidence, if any, was "likely unreliable." Dkt. 132 at 28 (citing *Khoja*, 899 F.3d at 1010 (failure to disclose that results had "high degree of uncertainty" made them "appear[] more promising [to investors] than [defendant] allegedly knew they were")). He asserts that statements asserting that a trial "demonstrated effectiveness imply that the resulting data is "empirically valid and analytically sound" are actionable if that data was instead the result of statistically unreliable analysis. *Id*. (citing *Frater*, 996 F. Supp. 2d at 346). He emphasizes he has plausibly alleged that CytoDyn misleadingly implied that the CD10 data was sound and that it demonstrated efficacy, and that it failed to disclose that it engaged in unreliable data manipulation. *Id*. (citing *In re Myriad Genetics, Inc. Sec. Litig.*, 2021 WL 977770, *8-9 (D. Utah Mar. 16, 2021) (statements about product's effectiveness misleading without statistically reliable efficacy evidence); *In re PTC Therapeutics, Inc. Sec. Litig.*, 2017 WL 3705801, *13 (D.N.J. Aug. 28, 2017) (statements claiming data demonstrated drug's efficacy actionable where "prespecified [] analysis *failed to produce such evidence*") (emphasis in original)). Courter argues it is also misleading to attempt to pass off post-hoc analyses without disclosing the true data, and the fact that it was using post-hoc analysis. *Id*. (citing *In re PTC Therapeutics, Inc. Sec. Litig.*, 2017 WL 3705801, *13 (D.N.J. Aug. 28, 2017)).

He argues that CytoDyn relied on just this sort of post-hoc analysis to "demonstrate" that Leronlimab was effective for COVID-19, despite knowing that the true data showed it was no more effective than a placebo, attempting to "lull" investors into thinking that the NEWS2 data was sufficient to meet FDA efficacy standards. *Id*. at 29–29 (citing *Frater*, 996 F. Supp. 2d at 343 (statements touting re-analysis of trial data

actionable where defendants did not disclose FDA's position that such post-hoc analysis "would not ordinarily support approval.")).

Courter also argues that after the FDA corresponded about CD10 in September and December 2020, CytoDyn made additional false and misleading statements about the results of that trial. He alleges the FDA privately told CytoDyn in September that CD10 "did not meet any of" its endpoints or "provide any [efficacy] evidence" and the FDA did "not recommend additional studies," but that CytoDyn responded by telling investors that "we have hit two endpoints and that CD10 "awarded us a pathway to approval."

Courter also plausibly alleges that the FDA told CytoDyn at the time that it was "relaying" "misinformation" because it was "not true" that CD10 met the NEWS2 endpoint. *Id.* at 29. Courter argues that CytoDyn's statements were misleading and untrue. *Id*. (citing *Khoja*, 899 F.3d at 1010 (defendants touting positive trial results have duty to disclose what FDA told them about results); *Arena*, 840 F.3d at 708 (representations that animal studies support approval actionable where defendants failed to disclose FDA's concerns about data); and *CV Therapeutics*, 2004 WL 1753251 at *8 (motion denied where defendants "failed to reveal the depth of the FDA's concerns")).

Courter also relies heavily on the FDA's "unprecedented" May 17, 2021 "Statement on Leronlimab," Dkt. 117-1. He argues that the FDA had warned CytoDyn in December 2020—five months after CytoDyn told investors that CD10 missed its primary endpoints—that "the public" was "likely to understand that CDA) actually met its endpoints," because of CytoDyn's misleading statements. He alleges that when the FDA's May 17 Statement "debunked" CytoDyn's public statements about CD10,

CytoDyn's stock price declined sharply. He argues, again persuasively, that the "truth" about the results of Leronlimab's clinical trials was not "in the marketplace" before the FDA's Statement. *Id*. at 30–31.

The Court again agrees with Courter. He has plausibly, specifically pled that CytoDyn falsely and misleadingly told investors that its CD10 trial demonstrated that Leronlimab was effective against COVID-19, and it had not. It misleadingly failed to disclose information that would have completed the context of the statements it did make.

CytoDyn's motion to dismiss Courter's Section 10b claim based on CytoDyn's CD10 statements is **DENIED.**

c. CytoDyn's CD12 statements.

Courter alleges that CytoDyn similarly made materially false and misleading statements about CD12 between March 5 and October 13, 2021. He alleges CytoDyn again told investors that CD12 demonstrated "statistically significant" results in several trial subgroups, and that, as a result, CytoDyn had: (1) pathways to FDA approval and was working with the FDA to expedite approval for COVID-19, and (2) had "filed" a "request" for a conditional EUA. Dkt 132 at 31. He argues that these statements were materially false and misleading: in truth, the FDA had twice rejected EUA, and warned CytoDyn that because the subgroup analyses were "post-hoc" and did not provide statistically reliable evidence, its public statements touting the results were "potentially misleading." CytoDyn even acknowledged privately to the FDA that it needed more data to statistically prove Leronlimab's efficacy. Dkt. 132 at 31.

Courter alleges that CytoDyn appreciated the gravity of the FDA's concerns yet publicly mischaracterized those concerns. It told investors that the FDA "saw" what they "saw" and that was a reason to go forward, when in truth the FDA questioned whether further evaluation of Leronlimab for COVID-19 was warranted. *Id*. at 32. He similarly alleges that CytoDyn told investors that the CD12 results were "good enough" for another trial, without disclosing that it in fact the FDA was willing to consider such a trial only if CytoDyn first demonstrated the scientific rationale with clinical data. Indeed, he claims, while CytoDyn told investors the FDA allowed it to extend CD12 to generate data for EUA or full approval, the FDA had already told CytoDyn that the data collected under the extension could not support approval. *Id*.

CytoDyn again argues that it disclosed the primary, relevant negative news about CD12 missing its endpoints, and that securities laws do not require issuers to focus on the most negative outcomes or unnecessarily disparage themselves. Dkt. 137 at 9. It argues that the market viewed CD12 as a failure and that in that context, its statements about CD12 were not misleading. Dkt. 116 at 14.

Courter responds that he isn't challenging CytoDyn's disclosure of CD12's failure to meet its endpoint, but rather its failure to disclose that its CD12 subgroup analyses were unreliable and would not support approval. He argues, and the Court agrees, that the "bad news" about the missed end point did not "counterbalance" the misleading impression created by the other statements and omissions. Investors were still led to believe that Leronlimab was effective against COVID-19—that it "worked." Dkt. 132 at 33 (citing *Warshaw v. Xoma Corp.,* 74 F. 3d 955, 958 (9th Cir. 1996) (claims sustained

where defendants reassured investors following FDA rejection of study about drug's effectiveness and likelihood of FDA approval)). The FDA's May 17 Statement on Leronlimab addressed the CD12 study, too, and similarly corrected the market's incorrect "impressions" about its efficacy. Courter argues that if investors understood that CD12 was a failure, the FDA would not have had to issue its Statement, and the stock price would not have plummeted when it did. Dkt. 132 at 34 (citing *Frater*, 996 F. Supp. 2d at 347 (requisite materiality demonstrated where stock price "plummeted" after "misleading statements were contradicted by the FDA")).

Finally, Courter emphasizes that CytoDyn's TOTM defense does not apply to Pourhassan's May 18, 2021, statement purporting to disclose the contents of non-public FDA correspondence without also disclosing the existence, date, and content of three prior private FDA letters denying EUA. *Id*. at 34 (citing *CV Therapeutics*, 2004 WL 1753251 at *8 ("once [defendant] started to reveal the contents of [his] conversations with the FDA, [he] had the duty to be truthful.")). He argues, correctly, that Pourhassan's claim that CytoDyn's prior CD12 statements were "not different" than the FDA's statement fraudulently downplayed the existence and significance of issues he and it had already discussed with the FDA. *Id*. (citing *CV Therapeutics*, 2004 WL 1753251 at *5). Courter has plausibly pled that a reasonable investor would be misled reading CytoDyn's statements, fairly and in context.

CytoDyn's motion to dismiss Courter's Section 10b claims based on its CD12 statements is **DENIED**.

3. The PSLRA Safe harbor.

CytoDyn argues that other statements are not actionable because they were "forward looking" and included the required cautionary language; they are within the PSLRA "safe harbor." It argues that the safe harbor bars claims based on challenged statements reflecting expectations or predictions where (i) the statements were identified as forward-looking and accompanied by meaningful cautionary language; or (ii) a plaintiff does not plead facts showing that defendants had actual knowledge that the statements were false when made. Dkt. 116 at 15 (citing *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.,* 759 F.3d 1051, 1058 (9th Cir. 2014), and *In re Daou Sys., Inc*., 411 F.3d 1006, 1021-22 (9th Cir. 2005)).

Courter responds that he does not challenge forward-looking statements about future aspirations, but rather his claims are based on present- and past-tense statements about Leronlimab and its "path to approval." Dkt. 132 at 35 (citing *Fibrogen, Inc.*, 2022 WL 2793032, at *7 and *8 (statements highlighting results "available at the time," and those regarding past interactions with FDA, are "not forward-looking."); and *In re MannKind Sec. Actions,* 835 F. Supp. 2d 797, 817 (C.D. Cal. 2011) (same)).

Courter also argues that CytoDyn's boilerplate cautionary language is insufficient to invoke the safe harbor; it is not substantive and is not tailored to the specific challenged projections, estimates, or opinions. *Id*. at 36 (citing *In re Amylin Pharmaceuticals, Inc. Securities Litigation,* 2003 WL 21500525 at *7 (S.D. Cal. May 1, 2003). He argues that cautionary language is not meaningful if it discusses as a mere possibility a risk that has already materialized. Specific statements about the future that

were untrue based on current events and knowledge are not forward looking, and are outside the safe harbor. *Id*. (citing *Forescout,* 2023 WL 2532061 at *23 ("[d]efendants cannot rely on boilerplate language describing *hypothetical* risks to avoid liability for the failure to disclose that the company *already* had information suggesting the merger might not ensue.")). He argues that CytoDyn warned that it "might not be able to provide acceptable evidence of efficacy" when the FDA had already rejected its May 2020 BLA submission, and CytoDyn had no other "acceptable" evidence to submit.

Statements that relate to events that already occurred, or which involve "predictions" that were not possible based on information CytoDyn already had, are actionable. To the extent CytoDyn's safe harbor argument applies to the statements discussed above, its motion is **DENIED**.

4. CytoDyn statements as opinion, puffery, or scientific disagreement.

CytoDyn similarly argues that some of its challenged statements[4] were expressions of opinion, "optimism," "mere puffery," or predictions of future events, and are not actionable. Dkt. 116 at 16–18.

It argues that statements including "We understand that the FDA's [sic] is requiring additional analysis of completed trials and results;" "I'm almost certain that [patients] have [been treated with leronlimab], as [the FDA] waived our waiting for pre-IND …. That's my guess;" and "In my humble opinion, there is no doubt that Leronlimab

[4] CytoDyn's motion includes a list of similar statements. Dkt. 116 at 17 n.11.

will be part of the future of COVID-19 therapies" are opinions, and that to be actionable they must be both subjectively and objectively untrue. Dkt. 116 at 17 (citing *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 176 (2015); and *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F. 3d 605, 615-16 (9th Cir. 2017)). CytoDyn argues that Courter has not plausibly pled that the speaker did not subjectively believe his statement's contents, and a prediction that turns out to be wrong does not render the statement untrue when made. *Id*. at 17–18 (citing *Yourish v. Cal. Amplifier*, 191 F.3d 983, 997 (9th Cir.1999) ("[i]t is clearly insufficient for plaintiffs to say that [a] later, sobering revelation[] makes[s] [an] earlier, cheerier statement a falsehood").

Courter argues first that he is not primarily challenging opinion statements; he is challenging statements that expressed certainty about a thing or occurrence: "No additional trials will be required;" "all the information the FDA has requested is obtainable.". He argues that such statements are not opinions. Dkt. 132 at 37 (citing *Omnicare* at 176 ("[A] statement of opinion conveys only an uncertain view as to that thing.")).

Courter also contends that some of CytoDyn's opinion statements are actionable, where he plausibly pleads

> (i) both that "the speaker did not hold the belief she professed" and that the belief is objectively untrue; (ii) that a fact contained within an opinion statement was untrue; or (iii) "facts going to the basis for the issuer's opinion," the omission of which rendered the statement misleading.

Dkt. 132 at 37 (citing *Align*, 856 F. 3d at 615-16)). He argues CytoDyn's opinion statements include embedded facts about the FDA's communications to it, what actions FDA took and why, and CytoDyn's NEWS2 data methodology, and that these facts can be proven untrue by documents CytoDyn possessed at the time. *Id*. at 38. He argues that CytoDyn said one thing about Leronlimab's COVID-19 MoA and efficacy but "held back" other material facts going to the basis of the statements, and that the statements are thus actionable. *Id*. (citing *Intuitive Sugical*, 2017 WL 4355072 at *4–5).

Courter has plausibly pled that, in context, the speaker could not have subjectively believed the factual underpinnings CytoDyn's "opinions;" the public statements did not fairly align with information in CytoDyn's possession. CytoDyn's motion to dismiss these statements as opinion is **DENIED**.

CytoDyn also argues that "mere puffery" is not actionable. It argues its optimistic expressions about Leronlimab's efficacy for HIV or COVID-19 are not capable of objective verification, and are thus not actionable. Dkt. 116 at 16 (citing, among others, *In re Alphabet, Inc. Sec. Litig.*, 1 F.4th 687, 700 (9th Cir. 2021) ("transparently aspirational" statements are inactionable because investors "know how to devalue the optimism of corporate executives")).

Courter responds, persuasively, that the statements he challenges are not mere puffery where CytoDyn was aware of facts rendering the optimistic statements false or misleading. Dkt. 132 at 40 (citing *In re Splunk Inc. Sec. Litig.,* 592 F. Supp. 3d 919, 941 (N.D. Cal. 2022). He also argues that expressions of optimism or confidence about trial data is actionable when it concerns and contradicts existing data undermining that

optimism. He argues that CytoDyn's statements about the eINDs conveyed false or misleading language about efficacy when the facts did not support any such claim. *Id*. And he argues that statements of "general optimism, when taken in context, may form a basis for a securities fraud claim." *Id*. (citing *Forescout,* 2023 WL 2532061 at *14).

The Court agrees. The same is true with respect to CytoDyn's argument that its statements reflected only "scientific disagreement" with the FDA. That is not what it told investors, and it has not argued or demonstrated why its optimism was warranted based on the data or its discussions with the FDA. It does not contend that it disagreed with the FDA, and indeed Courter has plausibly pled that CytoDyn acknowledged to the FDA that its data was not sufficient. CytoDyn's motion to dismiss its statements as mere puffery is **DENIED**.

5. Courter's Section 10(b) false statement claims against Kelly and Mulholland.

Kelly and Mulholland seek dismissal of Courter's Section 10b claims against them individually for the additional reason that the statements upon which he relies were, with two exceptions, not made by[5] either of them. Dkt. 116 at 20–22. They argue that Mulholland made none of the statements and that Courter's claim he participated in drafting them is insufficient: "playing "some role in the drafting, approving, and/or publishing of" allegedly false statements "is not enough to create liability under Section 10(b)." Dkt. 116 at 21 (citing *In re Impinj, Inc., Sec. Litig*., 414 F. Supp. 3d 1327, 1335

[5] Pourhassan joins the motion, Dkt. 123, but does not argue that he did not make the challenged statements; Courter has plausibly alleged that he did. His motion to dismiss Courter's claims on this basis is **DENIED**.

(W.D. Wash. 2019)). But *Impinj* cannot fairly be read so broadly. In context, the Court explained:

> The "maker" of a statement is "the person or entity with ultimate authority over the statement, including its content and whether and how to communicate it." [*Janus*, 564 U.S. at 143 and 145] A behind-the-scenes contributor to another's statement, such as a speech writer or one who provides false or misleading information that is incorporated into the statement, does not "make" the statement if the actual speaker or author ultimately controls the content and publication of the statement.

Impinj at 1335. Courter has plausibly pled that Mulholland had more that "some role" in drafting allegedly false and misleading statements CytoDyn submitted to the SEC; he signed them, repeatedly. And, as discussed below, Courter has plausibly pled that Kelly and Mulholland were CytoDyn control persons.

Kelly argues that his statements about the NEWS2 findings in CD10 were a non-actionable difference of opinion regarding the interpretation of the clinical trial data. *Id*. at 21–22. He argues Courter has not pled facts plausibly demonstrating that Kelly did not genuinely believe his opinion statements about Leronlimab. *Id*.

Courter responds that while he does not seek to hold Kelly or Mulholland liable under Section 10b for statements they did not make, he does plausibly plead that each routinely signed CytoDyn's SEC filings. Dkt. 132 at 20 n7 (citing *Howard v. Everex Sys., Inc.*, 228 F.3d 1057, 1061 & n.5 (9th Cir. 2000) ("a corporate official…who, acting with scienter, signs a[n] SEC filing containing misrepresentations, makes a statement" and is liable under Section 10(b)"). Courter's SAC and brief are also flush with other plausible allegations tying Kelly and Mulholland to CytoDyn's false and misleading statements.

The Court again agrees with Courter. Kelly and Mulholland's motion to dismiss Courter's Section 10b claims (Count I) against them is **DENIED**.

C. Count II – Section 10(b) stock promotion scheme (Rule 10b-5(a) and (c)).

Courter alleges that not only did CytoDyn, Kelly, Mulholland, and Pourhassan violate Section 10b and Rule 10b-5(b) by "making" false statements about Leronlimab and their efforts to obtain FDA approval to use it to treat HIV and COVID-19, he alleges a Rule 10b-5(a) and (c) claim based on defendants' fraudulent "scheme" to "promote" these statements, to maintain or increase the price of CytoDyn's stock. Dkt. 132 at 41. He asserts that during the first week of the class period, for example, CytoDyn issued seven COVID-19 press releases (PRs) containing misrepresentations, sent those PRs to promotional outlets and potential investors, and paid promotional outlets to amplify them. Dkt. 132 at 41. He alleges CytoDyn paid Proactive Investors to interview Pourhassan and Patterson[6] three times, and that they made additional misrepresentations during those interviews. *Id*. Courter alleges that the scheme worked: an analyst doubled its target price for CytoDyn stock; Pourhassan forwarded an article to a paid promoter "to distribute," and the promoter "blasted our biotech data base and cydy shareholders." *Id*. Courter alleges that on April 21, 2020, CytoDyn's stock closed above $3.00 for the first time in nine years, and that Pourhassan and Kelly internally acknowledged that the spike was the result of "people seeing" his interview on Yahoo finance. *Id*. And Courter asserts that

[6] Courter alleges that Dr. Patterson was a CytoDyn representative and consultant from October 2018 to May 2020. He is not a defendant, though Courter alleges he was CytoDyn's agent.

when the relevant truth was revealed, the stock price again declined, causing damage to investors. *Id*.

CytoDyn seeks dismissal of this claim, arguing that Courter fails to identify any loss to investors from the purported stock promotion scheme distinct from the stock price drops associated with the allegedly "corrective disclosures" of statements he challenges under Rule 10b-5(b). Dkt. 116 at 22 (citing *Stoneridge*, 552 U.S. at 159) (plaintiff must satisfy each of the elements for liability, including "(5) economic loss; and (6) loss causation")). CytoDyn argues that Courter's scheme claim is based on the same statements he already challenged under Rule 10b-5(b), and that he has not and cannot plausibly plead that the "promotion" of these statements affected the stock price separately from the market reaction to the statements themselves. *Id*. at 23.

It also asserts that press releases and reiterating third party statements are commonplace and lawful, and that it disclosed[7] its relationship with paid consultants. It argues there is nothing "inherently deceptive" about this conduct. *Id*. at 23–24 (citing *SEC v. Chen*, 2019 WL 652360, at *18 (W.D. Wash. Feb. 15, 2019)). It argues that Courter is required, and failed, to plead loss causation with particularity. *Id*. at 24 (citing *Oregon Pub. Emps. Ret. Fund*, 774 F.3d at 605 ("Rule 9(b) applies to all elements of a securities fraud action, including loss causation")). It argues that Courter has not demonstrated that Pourhassan's forwarding an allegedly misleading third-party video affected the stock price or caused damage to him. *Id*.

[7] Courter argues this "premature" factual dispute cannot be resolved on a motion to dismiss. Dkt. 132 at 44 n.33.

Courter responds that he is not required to allege "distinct" loss causation for claims under each subsection of Rule 10b-5. Instead, he asserts, his allegations of scienter, reliance, causation, and damages supporting liability under Section 10(b) are relevant to one or all of Rule 10b-5's sub-sections. *Id*. at 42 (citing *Lorenzo*, 139 S. Ct. at 1097, and *FirstEnergy*, 2022 WL 681320 at *26 ("Defendants' misrepresentations and omissions—and the presumptions that attach to them—are relevant for scheme liability")).

Courter identifies six "partially corrective events" that revealed the truth about CytoDyn's actual (lack of) progress in obtaining FDA approval for Leronlimab between March 5, 2020, and March 30, 2022, including: the incomplete BLA, the FDA's RTF letter, the fact CytoDyn had *not* requested EUA, the FDA's Statement on Leronlimab, and, ultimately, the clinical holds. He alleges, plausibly and accurately, that CytoDyn's stock declined each time the truth came out. He argues that he has plausibly pled causation for both his Rule 10b-5(b) and his Rule 10b-5(a&c) claims. Dkt. 132 at 43 (citing *Smith v. Lifevantage Corp.*, 341 F.R.D. 82, 107-08 (D. Utah 2022); and *FirstEnergy*, 2022 WL 681320 at *29 (finding causation for Rule 10b-5(a&c) conduct over "a series of disclosing events")). *Id*.

Courter also plausibly alleges that CytoDyn's conduct in drafting, disseminating, and repeating statements that CytoDyn, Mulholland, Kelly, and Pourhassan knew were false, are inherently deceptive acts. He argues his second amended complaint thoroughly catalogues the statements and why defendants knew they were false, how they impacted the stock price, and how the subsequent truth impacted that price. He accurately asserts

that he need only show "representative examples" of a "complex and far-reaching fraudulent scheme." *Id*. at 44 (citing *FirstEnergy*, 2022 WL 681320 at *1).

Courter also argues that CytoDyn is liable for the fraudulent conduct of Lalezari, Dhody, and Patterson, under traditional agency principles that apply in this context, even after *Janus Capital Grp., Inc. v. First Derivative Traders*, 564 U.S. 135 (2011). Dkt. 132 at 45-46 (citing *Glickenhaus & Co. v. Household Int'l, Inc.*, 787 F.3d 408, 426 (7th Cir. 2015) ("Nothing in *Janus* undid the long-standing rule that 'a corporation is liable for statements by employees who have apparent authority to make them.'").

CytoDyn correctly contends that it is not liable for any statements these non-parties made when they were not employed by CytoDyn, but it does not otherwise persuade the Court that it is not liable for its agent's false and misleading statements.

CytoDyn's motion to dismiss Courter's Rule 10b-5(a&c) "promotion scheme" claim (Count II) is **DENIED**.

D. Count III – Section 20(a) control person liability.

Courter alleges a Section 20a "control person" liability claim against Kelly, Mulholland, and Pourhassan, based on their Section 10(b) conduct. He correctly contends that to plead such a claim, he must allege (i) a Section 10(b) violation and (ii) that the defendant controlled the person liable for that violation. Dkt. 132 at 47 (citing *Alphabet*, 1 F. 4th at 701-702)). He emphasizes that whether a defendant is a "control person" is "an intensely factual question," and that Federal Rule of Civil Procedure 8(a)'s "relatively lenient" pleading standards apply to this claim. *Id*. (citing *Howard v. Everex Sys., Inc.,*

228 F.3d 1057, 1065 (9th Cir. 2000), and *Petrie v. Elec. Game Card Inc.*, 2011 WL 165402, *6 (C.D. Cal. Jan 12, 2011), respectively).

Kelly and Mulholland seek dismissal of this claim, arguing that even if Courter has plausibly pled the CytoDyn violated Section 10(b), he has failed to plead with particularity that either of them had the requisite control over the challenged conduct. Dkt. 116 at 25. They argue that in this context "control" means "the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract, or otherwise." *Id*. (citing 17 C.F.R. § 230.405). They argue that Courter's claim they "reviewed" and "approved" certain challenged statements "does not rise to a level of supervision or participation sufficient for a Section 20a violation." *Id*. (citing *Howard* at 1067 n.13). They point out that Courter has also alleged that Pourhassan (alone) exercised so much control over CytoDyn's operations that he "pushed out" board members who questioned his actions, suggesting that this implies that no one else possessed such control. *Id*.

The plausibility of Courter's claims about CytoDyn's Section 10b violations is discussed above. Courter argues he has adequately pled that each individual defendant controlled CytoDyn as corporate officers, and "were involved in drafting, producing, reviewing, and or dissemination of the allegedly false and misleading statements." Dkt. 132 at 48 (citing *Amgen* 544 F.Supp.2d at 1037)). He points out that *Howard*, the case upon which defendants' motion heavily relies, involved the *reversal* of an order dismissing a CEO because he "had authority over the process of preparing and releasing the financial statements," and he signed them. *Id*. (citing *Howard* at 1065). He argues that

Kelly and Mulholland did the same, and that he has similarly pled a plausible control person claim against them.

The Court again agrees with Courter. He has plausibly pled that Kelly, Mulholland, and Pourhassan "controlled" CytoDyn and are thus liable under Section 20a for the company's Section 10b violations. The individual defendants' motion to dismiss this claim (Count III) is **DENIED**.

E. Count IV – Section 20A insider trading.

Finally, Courter asserts a Section 20A insider trading claim against Kelly, Mulholland, and Pourhassan. He contends that each violated Section 10b, that each possessed material, non-public information (MNPI) when he sold CytoDyn stock, and that Courter (and the other named plaintiffs) engaged in "contemporaneous" trading activity. Dkt. 132 at 49 (citing *In re VeriFone Holdings, Inc. Sec. Litig.*, 704 F.3d 694, 711 (9th Cir. 2012).

The individual defendants seek dismissal of this claim. They argue that Courter must plausibly and specifically establish that that they each violated securities laws, each acted with scienter, and each sold CytoDyn stock while in possession of material, non-public information (MNPI). Dkt. 116 at 25 (citing *Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1035 (9th Cir. 2002) (plaintiff must plead scienter with particularity for Section 20A claim)). They argue that because Courter has failed to state a plausible Section 10(b) claim against them, his insider trading claim necessarily fails. *Id*. (citing *In re Petco Animal Supplies Inc. Sec. Litig.*, 2006 WL 6829623, at *35 (S.D. Cal. Aug. 1, 2006) (dismissing Section 20A claims against parties dismissed from Section 10b claims).

Defendants do not strenuously dispute that they possessed MNPI when they sold stock, and their latter argument is foreclosed by the Court's conclusion above that Courter has plausibly pled that Kelly, Mulholland, and Pourhassan violated Section 10b by making false and misleading statements with scienter.

Defendants also argue that Courter has not plausibly pled that Mulholland or Kelly[8] "actually used" the MNPI in making the alleged trades. Dkt. 116 at 26 (citing *In re Countrywide Fin. Corp. Sec. Litig.*, 588 F. Supp. 2d 1132, 1202-203 (C.D. Cal. 2008) (for Section 20A claim, "[s]cienter and loss causation … requires that the insider *actually use* … the inside information in deciding to make the trade").

Mulholland emphasizes that, as Courter concedes, his trades were pre-arranged under a Rule 10b5-1 trading plan not involving any discretion, rebutting any inference of scienter. *Id*. (citing *Metzler*, 540 F.3d at 1067 n.11, and *In re Nektar Therapeutics*, 2020 WL 3962004, at *16 (N.D. Cal. July 13, 2020) (sales made under Rule 10b5-1 trading plans weigh against "an inference of scienter"). Mulholland argues that by the time he committed to his trading plan, leading to the November 2020 sales at issue, CytoDyn had already disclosed, and the market had already reacted to, the material and major negative news of which Courter complains. Dkt. 116 at 26. He argues that the price at which he his pre-planned sales occurred—roughly 30% lower than the stock's class period high—undercuts any inference that the sales were "calculated to maximize the personal benefit from undisclosed inside information." *Id*. at 27 (citing *Ronconi v. Larkin*, 253 F.3d 423,

[8] Pourhassan joins this argument, Dkt. 123, but he does not articulate why Courter's claims against him similarly fail. His motion on this basis is **DENIED**.

435 (9th Cir. 2001) (sales do not support scienter "[w]hen insiders miss the boat this dramatically")).

Kelly argues that Courter has failed to plausibly plead that when he sold stock on May 1, 2020, he personally knew that the April 27 BLA submission did not include the clinical datasets that CytoDyn later submitted in May. He points out that the FDA's correspondence about that deficiency was sent to Amarex and Pourhassan, not to him. He claims Courter does not allege that it was then sent to him, much less that he received it before he traded. Dkt. 116 at 27.

Pourhassan joins Kelly and Mulholland's final argument that Courter has failed to plausibly plead that he "contemporaneously" traded with Kelly or Mulholland. They argue that this requires (or should require[9]) a plaintiff to allege that he traded on the "same day" as the insider, and that with limited exceptions, Courter has not so pled. *Id*. at 50 (citing *In re AST Research Sec. Litig*., 887 F. Supp. 231, 234 (C.D. Cal. 1995) (insider's sale and plaintiff's purchase must occur on the same day; "[t]he same day standard is the only reasonable standard given the way the stock market functions.")). It argues that the Courter has alleged only two same day trades, in which plaintiffs Hooper and McGee purchased CytoDyn stock at a price *lower* than Mulholland sold his stock. Dkt. 116 at 28.

Courter responds that the Ninth Circuit has not defined "contemporaneous" as "same day" trading, and that other district courts in the Circuit have more recently

[9] The Court declines CytoDyn's invitation to "adopt" the same day standard. Dkt. 137 at 16.

concluded that trades made withing days are sufficiently contemporaneous. Dkt. 132 at 49 (citing *Hefler v. Wells Fargo & Co.*, 2018 WL 1070116, *12 (N.D. Cal. Feb. 27, 2018) (two days); *Johnson v. Aljian*, 257 F.R.D. 587, 595 (C.D. Cal. 2009) (four days); *Evanston Police Pension Fund v. McKesson Corp.*, 411 F. Supp. 3d 580, 605 (N.D. Cal. 2019) (six days)).

Courter correctly contends that scienter is an element of the predicate Section 10b violation, but it is not a separate element of a derivative 20A claim. *Id*. at 49–50 (citing *VeriFone*, 704 F.3d at 711; and *Lipton* at 1035).

Courter asserts that, accordingly, he need not establish *why* the sales occurred, or that each seller "used" the MNPI in his possession; Section 20A requires only that a party *know* the inside information when he trades. *Id*. at 50 (citing *Thomas v. Magnachip Semiconductor Corp.*, 167 F. Supp. 3d 1029, 1050 (N.D. Cal. 2016) (rejecting *Countrywide*'s analysis, upon which Defendants rely); and *Steginsky v. Xcelera Inc.*, 741 F.3d 365, 370 (2d Cir. 2014) ("it is not necessary to show that corporate insiders *used* the nonpublic information; it is sufficient to prove that they traded their corporation's securities while knowingly in possession of [MNPI]").

The lack of a separate scienter requirement for 20A claims also undermines Mulholland's claim that the pre-planned nature of his sale his means he acted without discretion and thus without scienter. Courter argues persuasively that Courts have refused to dismiss on this basis because it would "require accepting 'proof of the disputable conclusion that [the Rule 10b5-1 plan] rule[s] out the possibility of trading based on

nonpublic material information.'" *Id*. (citing *McKesson*, 411 F. Supp. 3d at 605, n.3 (citing *Khoja*, 899 F.3d at 999)).

And finally, Courter argues that Kelly's discrete claim that he was unaware of specific MNPI about the FDA's view that CytoDyn's April 2020 BLA did not have required "clinical datasets" does not negate the plausibly-pled conclusion that he possessed ample MNPI about the BLA and the COVID-19 IND when he traded. *Id*.

The Court again agrees with Courter. Scienter is part of the predicate 10b violation, but it is not separately required with respect to a 20A sale made with MNPI. "Contemporaneous" does not necessarily mean "same day," and the fact that Mulholland's sale was pursuant to a Rule 10b5-1 plan is not a defense to a 20A claim, where Courter has plausibly pled a Section 10b violation and the possession of MNPI. The motion to dismiss Courter's 20A claim (Count IV) is **DENIED**.

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Courter's claims are plausible, measured against the heightened standard applicable to his SAC. Defendants' CytoDyn, Kelly, Mulholland and Pourhassan's motions to dismiss, Dkts. 116 and 123, are **DENIED**.

IT IS SO ORDERED.

Dated this 25th day of June, 2025.

BENJAMIN H. SETTLE
United States District Judge